

UNITED STATES OF AMERICA
DEPARTMENT OF JUSTICE
SUBPOENA DUCES TECUM

TO: Custodian of Records
Pharmasan Labs, Inc.
375 280th Street
Osceola , WI 54020

YOU ARE HEREBY COMMANDED TO APPEAR BEFORE Peter M. Jarosz, Assistant United States Attorney, an official of the U.S. Department of Justice, and you are hereby required to bring with you and produce the following:

the items described on the attachment to this subpoena

which materials are necessary in the performance of the responsibility of the U.S. Department of Justice to investigate federal health care offenses, defined in 18 U.S.C. § 24(a) to mean violation of, or conspiracies to violate: 18 U.S.C. §§ 669, 1035, 1347 or 1518; and 18 U.S.C. §§ 287, 371, 666, 1001, 1027, 1341, 1343, or 1954 if the violation or conspiracy relates to a health care benefit program (defined in 18 U.S.C. § 24(b)).

PLACE AND TIME FOR APPEARANCE: At the Office of the United States Attorney, 660 W. Washington Avenue, Ste 303, Madison, Wisconsin, 53701 on the 19th day March, 2014, at 9:00 AM.

Failure to comply with the requirements of this subpoena will render you liable to proceedings in the district court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience. **In lieu of appearing with the requested items and records before the undersigned official, the subpoenaed material may be delivered on or before the above-stated date and time to Peter M. Jarosz, Assistant United States Attorney, Office of the United States Attorney for the Western District of Wisconsin, 660 W. Washington Avenue, Ste 303, Madison, Wisconsin 53701 who can be reached at (608) 264-5158.**

Issued under authority of Section 248 of the Health Insurance
Portability & Accountability Act of 1996, Public Law No. 104-91
(18 U.S.C. § 3486)



IN TESTIMONY WHEREOF


Jeff Anderson, First Assistant United States Attorney

The undersigned official of the U.S. DEPARTMENT OF JUSTICE, has
hereunto set her hand this 10th day of March, 2013.

AID No. AID-WIW-2014-0002
USAO No. 2012R000285

(SIGNATURE)

RETURN OF SERVICE

RECEIVED BY SERVER	DATE 3/12/2014	PLACE 373 280 th St, Osceola, WI
SERVED	DATE 3/12/2014 ~ 11:15 AM	PLACE 373 280 th St, Osceola, WI
SERVED ON (PRINT NAME) Atty. Henry M. Helgen, III c: 612-735-7198		
SERVED BY (PRINT NAME) KEVIN R. OLLENDICK		TITLE SPECIAL AGENT
STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES	TOTAL
DECLARATION OF SERVER		
<p>I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <p>Executed on <u>3/14/2014</u>  Date Signature of Server</p> <p><u>Madison, WI</u> Address of Server</p>		
ADDITIONAL INFORMATION		

AID No. AID-2014-WIW-0002

Instructions

1. These requests apply to all records in your possession, custody, or control regardless of their location and regardless of whether such documents are held by your attorneys, consultants, accountants, investigators, representatives or agents, or any other person acting on your behalf.

2. These requests are continuing in nature. If you become aware of or acquire possession, custody, or control of additional responsive records, you shall promptly produce such additional records for inspection and copying.

3. If any records are withheld based upon a claim of privilege, work product doctrine, or any other protection from disclosure:

- a. identify the document in writing;
- b. state the privilege(s), work product doctrine(s), or other protection(s) from discovery relied upon for withholding the document; and
- c. state all facts supporting the claim of privilege(s), work product doctrine(s), or other protection(s) from discovery.

4. Identify records responsive to this request that have been lost, discarded, or destroyed. In so doing, state the type of document, its date, the approximate date it was lost, discarded, or destroyed, and the identity of each person having knowledge of the contents thereof.

AID No. AID-2014-WIW-0002

Definitions

1. "You" or "Your" shall mean Pharmasan Labs, Inc., and its parent, subsidiaries, related entities, divisions, and any other person or entity acting on its behalf.
2. "Records" is used in the broadest possible sense and means the originals (or any copies when originals are not available) and any nonidentical copies of any written, printed, typed, photostatic, photographed, recorded or otherwise reproduced Communication or representation of every kind, whether internal or external, and including correspondence, notes, minutes, records, messages, memoranda, diaries, reports, studies, summaries, analyses, financial statements, working papers, maps, diagrams, charts, plans, pictures, electronic data or electronically stored information, computer printouts, all other data compilations from which information or Communications can be obtained, and any versions, drafts or revisions of any of the above. Record includes the file and folder tabs associated with each original and/or copy, all correspondence transmitting such Record or explaining or commenting on its contents, and all other supporting papers.
3. "Relating to" or "relate" shall mean consisting of, referring to, reflecting, supporting, evidencing, prepared in connection with, used in preparation for, or being in any way legally, logically, or factually connected to the matter discussed.
4. "And," "or," and "and/or" shall be construed either disjunctively or conjunctively so as to bring within the scope of these record requests any information which might otherwise be construed as outside their scope.
5. The singular and plurals forms of any word shall be construed interchangeably so as to bring within the scope of these document requests any information which might otherwise be construed as outside their scope.
6. "Including" means including without limitation.

AID No. AID-2014-WIW-0002
Records Request

You are required by this Demand to produce any and all of the following Records in Your custody or control:

The following records generated, stored, or received between, or relevant to the time period, January 1, 2008 through the present that pertain to Pharmasan Labs, Inc. ("Pharmasan") or NeuroScience, Inc. ("NeuroScience").

1. Any records relating to the employment of individuals responsible for billing or creating policies for billing laboratory services payable by Medicare, including but not limited to,
 - a. employment lists or organization charts identifying individuals responsible for Medicare billing,
 - b. job descriptions,
 - c. training materials,
 - d. performance reviews, and
 - e. communications including electronically stored communications relating to employees' submission of claims to Medicare or creation of policies for the submission of claims to Medicare.
2. Any records relating to the employment of individuals responsible for interpreting or modifying Pharmasan laboratory test results, including but not limited to,
 - a. employment lists or organization charts identifying individuals responsible for interpreting or modifying Pharmasan laboratory test results,
 - b. job descriptions,
 - c. training materials,
 - d. performance reviews, and
 - e. communications including electronically stored communications relating to employees' interpretation or modification of Pharmasan laboratory test results.

3. Any records relating to revenue and expenses associated with the rendering of laboratory services payable by Medicare, including but not limited to,
 - a. spreadsheets disclosing patients or providers and revenues generated by such customers,
 - b. memoranda, reports, analyses, or summaries of testing payable by Medicare and amounts received for such testing,
 - c. accounting records relating to amounts received from Medicare, and
 - d. communications including electronically stored communications relating to revenue and expenses associated with the rendering of laboratory services payable by Medicare.
4. Any records relating to revenue and expenses associated with the interpretation or modification of laboratory test results, including but not limited to,
 - a. memoranda, reports, or analyses relating to NeuroScience product sales and Pharmasan test results and/or recommendations and
 - b. communications including electronically stored communications relating to revenue and expenses associated with the interpretation or modification of laboratory test results.
5. Any records relating to the method of submitting claims for reimbursement of laboratory services to Medicare and requirements relating to the same, including but not limited to,
 - a. billing or coding policies or handbooks,
 - b. local coverage determinations,
 - c. national coverage determinations,
 - d. Medicare educational materials,
 - e. CPT coding guidance,
 - f. compliance program reviews or audits of CPT coding or Medicare billing,
 - g. laboratory testing protocols and any document showing CPT codes associated with the testing protocols,
 - h. Medicare provider enrollment documentation and agreements, and

- i. communications including electronically stored communications relating to the requirements for, and method of, submitting claims for reimbursement of laboratory services to Medicare.
- 6. Any records relating to Pharmasan's role in interpreting test results and recommending NeuroScience products, and its modification of test results, including but not limited to,
 - a. records of original and modified test results,
 - b. memoranda addressing Pharmasan's ability to modify lab test results,
 - c. scientific data or studies supporting any modification of lab test results,
 - d. communications with manufacturers of testing relating to the modification of lab test results,
 - e. documents that discuss the reference range for laboratory tests,
 - f. communications with CLIA or other regulators relating to the modification of lab test results,
 - g. memoranda, reports, or analyses of CLIA requirements and their application to the modification of test results,
 - h. memoranda, reports, or analyses addressing NeuroScience product sales affected by Pharmasan's interpretation of test results, and
 - i. communications including electronically stored communications relating to Pharmasan's role in interpreting test results and recommending NeuroScience products, and its modification of test results.
- 7. Any records consisting of or discussing business plans, projections, or workflows relating to the submission of claims to Medicare or relating to affecting NeuroScience product sales through Pharmasan business operations, including but not limited to,
 - a. budgets,
 - b. business models,
 - c. memoranda, reports or analyses addressing increasing revenue from Medicare,
 - d. memoranda, reports or analyses addressing target groups of customers or providers,

- e. business marketing plans relating to the sale of NeuroScience products,
 - f. business marketing plans relating to the sale of laboratory services to Medicare beneficiaries or providers of Medicare beneficiaries, and
 - g. communications including electronically stored communications addressing business plans, projections, or workflows relating to the submission of claims to Medicare, or relating to affecting NeuroScience product sales through Pharmasan business operations.
8. Medicare beneficiary medical records and record of laboratory services, including but not limited to,
- a. requisition or order forms for testing,
 - b. records of laboratory services performed, draft and final test result reports,
 - c. medical records supporting the medical necessity of laboratory services performed, and
 - d. documents relating to the referring provider's ability to order laboratory testing for the Medicare beneficiary.
9. Regulatory compliance records, including but not limited to,
- a. memoranda, reports or analyses generated or kept by any employees ensuring Pharmasan's compliance with Medicare rules and regulations and CLIA rules and regulations,
 - b. memoranda, reports or analyses generated by outside consultants relating to Pharmasan's compliance with Medicare rules and regulations and CLIA rules and regulations, and
 - c. communications including electronically stored communications relating to regulatory compliance.
10. Records relating to Pharmasan's relationship with providers that refer services to Pharmasan, including but not limited,
- a. contracts with providers,
 - b. sales documentation given to providers relating to services, products, and Medicare reimbursement,

- c. new account set up forms, account update forms, and account change forms, and
 - d. communications including electronically stored communications between Pharmasan and providers relating to Medicare billing.
11. All records consisting of marketing materials distributed to medical providers relating to laboratory testing services, and/or NeuroScience's products or services.
 12. All records relating to any sales programs in which Pharmasan waives its ability to collect payment from a beneficiary of a federal healthcare program, including Federal Employee Health Benefit Programs, TRICARE, TRICARE Plus, Medicare, and Medicaid.
 13. All records relating to any sales programs in which Pharmasan offers free laboratory testing services to certain providers.
 14. All records showing remuneration of any kind offered or paid to any provider that orders laboratory testing services from Pharmasan, and documents showing the reason for such offer or payment.
 15. Listing of any persons paid to promote NeuroScience and/or Pharmasan products or services.
 16. All records tracking sales of NeuroScience products by Pharmasan referring providers.
 17. All records showing the reasons for repayment of any sums to Medicare.
 18. All records comprising training manuals for billing, laboratory, and sales staff.
 19. All records relating to, for Pharmasan claims for reimbursement, repayment of any sums to private insurers, denial letters from private insurers, and educational letters from private insurers.